REMARKS

Prior to the present Office Action, claims 1-10, 13-18, 21-23, and 31-41 were pending, and claims 11-12, 19-20, and 24-30 were canceled. Claims 42-45 are added, and therefore claims 1-10, 13-18, 21-23, and 31-45 are presently pending.

Applicants gratefully acknowledge the allowance of claims 31-41.

Claims 1-4, 6-7, 9-10, 13-18, and 22-23 stand rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 4,501,030 to Lane in view of U.S. Patent No. 5,855,601 to Bessler. Initially, Applicants presume the Examiner intended to reject these claims under 35 USC §103(a) as being an obvious combination of the two cited references, as there can be no anticipation using such a combination.

Additionally, Applicants note that in the previous amendment the limitations of certain dependent claims were added to claims 1 and 13 to render them allowable, because those dependent claims had not been rejected. Claims 1 and 13 had been deemed anticipated by Lane alone. Now, the Examiner combines Bessler with Lane to reject amended claims 1 and 13. Because the limitations were only added on the basis that they presumably rendered claims 1 and 13 allowable, they are now deleted from claims 1 and 13 and Applicants will address the earlier anticipation rejection solely on the basis of Lane.

Original dependent claims 11-12 and 19-20 are refiled as new claims 42-45, respectively. Applicants wish to point out that the valve of Bessler is collapsible for which a highly flexible Nitinol stent is extremely useful. However, the frame 13 of Lane is described as being "constructed of various biocompatible materials, such as suitable metals, plastics or composite fibrous materials. For example, a suitable cobalt alloy, a polyolefin or a carbon reinforced, non-metallic material may be used." The frame commissures are cantilevered into the flow stream and designed to withstand the inward forces of valve closure. One of skill in the art would not substitute a flexible material such as Nitinol for such a frame. Note that the valve of the present invention is designed to attach around the periphery of the stent, and thus the stent commissures are not cantilevered into the flow stream and can be made very flexible.

In any event, Applicants strenuously disagree with the application of Lane, in particular using an "intermediate product" shown in Lane. Claims 1 and 13 both provide a prosthetic heart valve including a suture-permeable band attached to the stent providing an interface between the valve and surrounding host tissue. In claim 1 the connecting band closely conforms to the alternating stent cusps and commissures and defines an axial gap along the commissures opening in the inflow direction for enhancing freedom of movement of the stent cusps. In claim 13 the suture-permeable band has a shape that mimics the alternating stent cusps and commissures and is attached along the undulating periphery of the stent so as to project outward from the stent along the stent cusps and commissures and provide an interface between the assembled valve and surrounding host tissue. For emphasis, both claims now define the band as providing a valve/tissue interface in the *assembled valve*.

In contrast, the structure cited by the Examiner in Lane is not a suturing band, nor does it provide a valve/tissue interface in the assembled valve. Specifically, the Examiner points to "band 48" in Fig. 15 of Lane. The following passages in Lane are the only mention of element 48:

> Next, the frame 13 is covered with a fabric cover 43, and the cover is attached to the frame in any suitable manner, such as by sutures 45. This forms a subassembly which has three recesses 47 which open away from the associated reverse bend, i.e., downwardly as viewed in FIG. 9. As shown in FIG. 10, the cover 43 completely encloses the wire frame 13 and has a ***pair of flaps 48*** which extend radially outwardly of the frame. (col. 5, lines 50-57)
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> ...
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> With the two subassemblies in the position shown in FIG. 15, they are attached to each other, and this is preferably carried out in two stages. In the first stage, the supports 49 are attached to the associated commissure supports 19, 21 and 23 in any suitable manner, such as by a suture 76 which is passed through the tab 67 of the valve leaflets 15, 15a, the skirt 63, the suture holes 57 and 59, and passed over the reverse bend 31. This is done several times, and the suture is then suitably tied off. This initial attachment step holds the two subassemblies together in the proper orientation so that a marginal portion of the valve leaflets 15, 15a and 15b lying along the elliptical edges 69 can be attached to the cover 43 as by sewing utilizing a suture 77 as shown in FIG. 16. To enable the heart valve to be implanted in a heart, the ***suture ring 17*** is then attached to the frame 13 in any suitable manner, such as by sewing it to the cover 43, ***the flaps 48 are sewed closed***, and

> woven cloth 78 (FIG. 16) is sewed to the outside faces of the flaps to form the configuration of FIG. 1. (para. bridging cols. 6 and 7)

Instead of a valve/tissue interface in the assembled valve, element 48 is a flap of a fabric cover around the inner skeletal frame 13. The flap 48 is used to secure the frame 13 to the tissue leaflets. That is, the "two subassemblies in the position shown in FIG. 15" are the "subassembly of FIG. 14" and "the subassembly of FIG. 9." (Col. 6, lines 55-58) The subassembly of Fig. 14 comprises leaflets sewn to resilient supports 49, while the subassembly of Fig. 9 is the frame 13 covered with a fabric cover 43. The flap 48 is a cloth cover for the frame which is completely internal in the assembled valve, as seen in Fig. 1. Therefore, flap 48 does not anticipate the bands of claim 1 and 13 which are external to the assembled valve and provide valve/tissue interfaces.

Lane discloses a valve/tissue interface in the form of a suture ring 17, as described at col. 7, lines 12-17, reprinted above. The suture ring 17 is shown in Fig. 1. Applicants assert that the connecting band of claim 1 and suture-permeable band of claim 13 are not disclosed nor suggested by Lane. Namely, the suture ring 17 in Lane does not closely conform to the alternating stent cusps and commissures, or define an axial gap along the commissures opening in the inflow direction for enhancing freedom of movement of the stent cusps, or have a shape that mimics the alternating stent cusps and commissures, nor is it attached along the undulating periphery of the stent so as to project outward from the stent along the stent cusps and commissures. Accordingly, claims 1 and 13 are believed allowable over Lane. Dependent claims 2-10, 14-18, 21-23, and 42-45 are also believed allowable.

Fees Due to File This Amendment

Prior to the pending Office Action, fees were paid for a total of 30 claims, with 4 of them being independent claims. The aforementioned claim additions and cancellations have resulted in 34 total claims, 4 of them independent. Accordingly, the Commissioner is hereby authorized to

charge the required fee of $200.00 for 4 additional dependent claims to Deposit Account No. 50-1225 (Docket No. ECV-5413CIP2CON1). If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

CONCLUSION

In conclusion, the foregoing amendments and remarks are believed to place claims 1-10, 13-18, 21-23, and 31-45 into condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged to contact the undersigned by telephone.

Respectfully submitted,

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